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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,513	12/21/2001	Juan Mantelle	041457-0630	4098

22428 7590 08/18/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

CHOL FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

**Advisory Action**

Application No.

10/024,513

Applicant(s)

MANTELL ET AL.

Examiner

Frank I Choi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 June 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.


Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.

10. ☐ Other: \_\_\_\_\_

  
**S. MARK CLARDY**  
**PATENT EXAMINER**  
**GROUP 1200**  
1616

Continuation of 2. NOTE: The proposed amendments raise new issues in that now Applicant presents an affidavit pursuant to Rule 131 to antedate a reference which was cited in the first Office Action in the present Application. Further, the affidavit appears to be deficient in a number of aspects, including Applicant has not provided good and sufficient reasons why the affidavit was not presented earlier, there is no indication that any study was performed in the US, WTO or GATT country, and the figures do not appear to constitute evidence of actual reduction to practice as there is no indication as to the amount of methylphenidate contained in the patch, there is no indication that there is an adhesive or what the adhesive is or amounts thereof, there is no indication as to the amount of ritalinic acid, there is no indication as to the rate of delivery of the methylphenidate over a period of 24 hours, there is no indication that there is less than about 5% w/w of acid functional monomers, there is no indication as to treatment of attention deficit disorder and attention deficit/hyperactivity disorder and there is no evidence of records of data and results which were obtained or performed prior to the relevant date upon which said figures are based. Further, the evidence does not appear to be commensurate in scope with the claimed invention in that the figures appear to be related to working examples in the Specification which contained specified amounts of methylphenidate, specific adhesives and amounts thereof and tested normal individuals whereas the claims are broader in scope with respect to amounts of the components, the type of components and claim aspects which do not appear to set forth in the evidence provided as indicated above.

Continuation of 5. does NOT place the application in condition for allowance because: the affidavit has not been considered and the amendment has not been entered for the reasons set forth in item nos. 2 and 6, as such, the rejections set forth in the prior Office Actions are maintained .